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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,644	12/20/2001	Robert Cherney	PH-7269	1479

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STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/19/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,644

Applicant(s)

CHERNEY, ROBERT

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) 1-15 and 25 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 1-25 are pending in this application.

The election of example 1, page 186, with traversal in Paper No. 7, filed 1/8/03, is hereby acknowledged. The traversal is on the basis of reasons set forth in the MPEP. Since no specific reason is given, the traversal is deemed made without a reason.

The restriction is still proper and therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-24, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases such in the claims, does not reasonably provide enablement for their "prevention". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The asserted utility is not believable on its face. There is no known compound for the prevention of all the diseases, and the specification does not provide sufficient enabling disclosure for the claimed utility.

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.

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- 5) Level predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention involve the use of compounds of formulae I. The nature of the invention is in the field of medicinal chemistry wherein applicant is claiming the methods of use of the compounds for the prevention of all the diseases listed in the claims.

The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art claiming the prevention of all the diseases. The level of ordinary skill in the art is high but only in the art of treating of all theses diseases. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assays involving: 1) Antagonism of MCP-1 binding to human PBMC, 2) Antagonism of MCP-1-induced calcium influx, and 3) Antagonism of MCP-1 binding to human PBMC chemotaxis. There is no evidence in the specification that established correlation between the experiments and prevention of all the listed diseases. See Ex parte Mass, 9 USPQ2d 1746, 1987. Therefore, the quantity of experimentation required to use the compounds as claimed in the instant invention, based on applicants limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of in-vivo

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experiments as well as additional in-vitro assays. By deleting "prevention" from the claims, the rejection would be overcome.

Allowable Subject Matter

To place claims 1-15, 25, in condition for allowance applicant must amend the compound claims as follows:

B is a saturated cycloalkyl having 6 carbon atoms; s is 0; R9, R1a, R1b, are each H. R1, R2, R8, R10, R10a, R11, R12, Z, and n are as defined in claim 1, wherein morpholine, piperidine, azetidine and pyrrolidine are the only heterocyclic substituents. R13 and m are not applicable. *m = 0*

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626

March 13, 2003

*Fax 609 252 4526
Mary Van Apleen*